SUBJECT:	Fermilab Assessment Manual – Chapter 4 Independent QA Assessment Procedure – Form 2	**NUMBER:**	3902.1004 FORM 2
RESPONSIBILITY:	Quality Assurance Manager	**REVISION:**	001.4
APPROVED BY:	Head, Office of Quality and Best Practices	**EFFECTIVE:**	11/15/2011

Fermilab Independent QA Assessment Report

Assessment Number & Title: 11-IA-QA-012 PD-M&TE **Version:** 1

Date(s) of Assessment: 08/15/11 – 08/18/11

Performing Organization: Office of Quality & Best Practices

Assessed Organization(s): Particle Physics Division (PPD) including the following:

- Technical Centers
  - Alignment & Metrology
  - Precision Metrology
- Mechanical Department
  - Engineering Analysis
  - Vacuum & Instrumentation
- ES&H Group
- Neutrino Department (NOvA)

Assessment Activities & Scope:

Implementation and effectiveness of controls for Measuring and Test Equipment (M&TE) relative to the requirements of Integrated Quality Assurance (IQA) were examined via interview, observation, and document & record review. These controls were examined across the PPD departments, centers, and groups listed in the "Assessed Organization(s)" section of this report.

Scope Limitations:

The scope of this assessment was limited to the departments, centers, and groups listed in the "Assessed Organization(s)" section of this report.

Activities Reviewed Within this Assessment:

- Alignment & Metrology calibration system
- Precision Metrology calibration system
- Engineering Analysis practices
- Vacuum & Instrumentation calibration practices
- ES&H calibration practices
- NOvA calibration practices

Description of the Implementation & Effectiveness of Observed Activities:

Measuring and Test Equipment:
M&TE requirements found in IQA chapters five and eight have been partially implemented within the PPD departments assessed. Two exceptions are described in the Findings section of this report. M&TE used for inspection, test, process monitoring, and data collection are identified, calibrated, maintained and controlled commensurate with their intended use. However this control varies between areas assessed.

"PPD_ADMIN_029 Calibration Policy & Procedure for the Control of Measurement & Test Equipment" has been fully implemented in three areas assessed, and partially implemented in three other areas assessed.

Technical Centers provide support for the development of new technology required for experiments.

- Alignment & Metrology provides precise alignment of beam controlling equipment, and calibrates this equipment. There is a database containing an instrument inventory for survey & alignment (File 1) as well as a manual of instructions of how to calibrate these instruments (File 2). Records of the calibration results are kept in a shared drive (File 3). Data from suppliers contracted to do calibration is also available (File 4). Equipment that is rarely used is labeled "for reference only" or "calibrate before use" and stored in a separate rack of their equipment storage area. At this time, the general practice is to calibrate all equipment before use, as the older equipment is rarely used, and the newer laser trackers self-calibrate before each use. In the event the self-calibration returns an error message, the unit is withdrawn from service & sent to the supplier for calibration/adjustment/repair. While observing a DNA03 Laser Tracker identified as "Rosie" an out of date calibration status sticker was identified on the case. This unit was labeled for calibration before use, but also had a sticker with a calibration due date of Sept 2010.

- Precision Metrology provides the design and development of various types of R&D equipment and the preparation of technical reports for R&D activities and inspectional functions as well as other activities (File 5). The equipment sampled is located in the clean room. Precision Metrology has fewer tasks currently than in the past. This is represented by the fact that 4 Coordinate Measuring Machines (CMM) have been transferred to other facilities for re-use as stated by the person interviewed. As a result, instruments are used less frequently. The CMMs observed had labels that warned that the calibration of the CMM had to be checked by going to a referenced website (example: Cordax 1808 MEA ser# C-6391-3-93). If the calibration was over 6 months old, it needed to be calibrated before use (File 6). The general practice for other equipment such as optical comparators (example: AVANT 600FOV ser# AVG001205 commonly called "OGPs") is to calibrate before use (File 7) due to infrequent use. Equipment that was identified as not belonging to Precision Metrology was observed. This equipment had no evidence of being calibrated. Persons interviewed stated that these items were the responsibility of the specific experiment or project & were kept in a separate area from the Precision Metrology equipment.

The Mechanical Department supports research by providing designs, Finite Element Analysis (FEA) and stress analysis among other services.

- Engineering Analysis provides computer modeling via Finite Element Analysis (FEA) for new designs and changes in current designs. No M&TE is used by the Engineering Analysis organization. Physical verification of the computer models is the responsibility of the experiment or project. When the physical measurements are provided to the Analysis group, the FEA model is modified as necessary.

- Vacuum & Instrumentation (V&I) supplies equipment to measure vacuum for experiments. V&I personnel calibrate and adjust relief valves, gauges, transducers, and other items. All items

calibrated by V&I staff are returned to the owner (File 8) along with records of work performed. The item either passes, passes after adjustment, or fails. If an item can't be adjusted into calibration, it is the responsibility of the owner to either discard, or repair the item as described in the attached flowchart (File 8). Records of calibration are kept in a shared drive, and hard copies are also filed on site (File 9). Equipment used to calibrate items are calibrated by an outside supplier (File 10) and are traceable to NIST.

ES&H is responsible for advising activities to ensure compliance with safety and health requirements including gas detection.

- Gas detection is performed whenever personnel are required to enter an enclosed space. They use the same gas detection procedures as the Fermilab Fire Department and the gas detector is calibrated before each use (File 11).

The primary mission of the Neutrino Department is to support the Fermilab Neutrino Physics Program (File 12).

- The NOvA experiment maintains an estimated over five hundred calibration procedures and records for individual items. These procedures and records are stored on a shared drive (File 13). The list of procedures on the shared drive was observed during the interview. Not all items used by NOvA are owned by Fermilab. Many are brought by visiting scientists. During the interview, a Kiethly 6517A high resistance meter had a calibration sticker on its case with a date that was past due. A personally owned set of calipers was observed during the interview. The only record of calibration was the documentation provided when the calipers were new. The person interviewed stated that the calipers were over a year and a half old, and loaned out as needed. There was no calibration sticker on the calipers or box. Further investigation during a subsequent interview with another person revealed a depth micrometer approximately two weeks old owned by Fermilab without a calibration sticker on the box or the instrument.

Conclusions:

There is no PPD-wide M&TE program however PPD does have a M&TE policy that is partially implemented. The practice of "calibrate before use" appears to be the standard practice and an extensive database and shared drives which included calibration instructions and records supports this. Three out of six departments assessed did not fully comply with PPD_ADMIN_029 section 4.2 M&TE. Specifically calibration labels were either nonexistent or out of date. Equipment used for reference only was not labeled as such. In two departments, equipment was observed that does not belong to PPD and had no indication of calibration status.

Findings:

In three out of six departments assessed, calibration labels were either nonexistent or out of date. Equipment used for reference only was not labeled as such. This is contrary to the requirements of IQA chapter 8 and "PPD_ADMIN_029 para 4.2 Calibrating M&TE".

- While observing a DNA03 Laser Tracker identified as "Rosie" in Alignment & Metrology, a calibration status sticker with a due date of Sept. 2010 was identified on the case.

- In the Neutrino Department a Kiethly 6517A high resistance meter had a calibration sticker on its case with a date of 7/2007. A personally owned set of unbranded 8" calipers was observed during the interview. There was no calibration sticker on the calipers or box.

It is the responsibility of PPD line management to "ensure that the equipment meets the accuracy, precision, performance and safety requirements required for the task." (PPD_ADMIN_029) "PPD_ADMIN_029 para 4.2 Calibrating M&TE" states that any item with a calibration sticker is controlled.

Observations and Recommendations:

1. **Observation:** M&TE in Precision Metrology not owned by Fermilab is being used to build and test equipment used in experiments. This equipment does not appear to be controlled with regards to IQA requirements and the PPD policy on M&TE.
   Recommendation: Identify equipment used and include in the calibration database. Replace personal equipment with Fermilab equipment (personal calipers, micrometers etc.) or incorporate them into a PPD calibration activity.

Commendable Practices:

None

Persons Interviewed:
Bob Barger
Rob Bushek
Horst Friedsan
Mike Roman
Rick Tesarak
Bob Wands

Documents Reviewed:

- PPD_ADMIN_029 "Calibration Policy & Procedure for the Control of Measurement & Test Equipment"
- ESH-012 Calibration Procedure Guidelines for PPD/ESH
- Survey and Alignment Group Instrument Inventory database
- Flowchart for vacuum testing
- Tintometer Testing Procedures2.pdf

Attachments:

- File 1 Survey & Alignment Inventory
- File 2 Procedures Table of Contents
- File 3 Calibration Report
- File 4 Certificate of Calibration
- File 5 Precision Metrology
- File 6 Ball Bar Results
- File 7 OGP Calibration

- File 8 Flowchart
- File 9 Deadweight Check
- File 10 Certified Calibration Certificate
- File 11 Air Monitoring Equipment Data
- File 12 Mission Statement
- File 13 Procedures & Data

Standards, Regulations, and Other Program Requirements Applied:

The specific criteria applied to this assessment were:

1001 IQA section 5.4.2, Maintenance (relative to M&TE)
1001 IQA section 5.4.4, Calibration of Process Equipment
1001 IQA section 8.5, Control of Measuring &Test Equipment
PPD_ADMIN_029 Rev 07/08/2009 Calibration Policy & Procedure for the Control of Measurement & Test Equipment

Corrective Action Plans Issued: PD-2011-09-21-1 Measuring & Test Equipment

Assessors' Names (asterisk indicates team leader):

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Submitted by: T. Gehrke **Date:** 09/22/11

Distribution (Distribute to assessed organizations' management, OQBP head, and other interested parties):

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